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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/177,427	10/22/1998	STEFAN LUKAS	4804-4	3113

7590

10/08/2002

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EXAMINER

BERMAN, ALYSIA

ART UNIT

PAPER NUMBER

1617

DATE MAILED: 10/08/2002

34

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/177,427

Applicant(s)

LUKAS ET AL.

Examiner

Alysia Berman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 January 2002 and 29 April 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 16-30 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 16-30 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

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DETAILED ACTION

1. Receipt of the amendment filed January 16, 2002 is acknowledged. Claims 16 and 27 have been amended. Claims 16-30 are pending.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. The 35 U.S.C. 102(b) rejection are withdrawn because the prior art does not disclose every limitation of the claims as arranged in the claims. CA '366 does not disclose the aspect ratio or shape of the particles and US '411 does not disclose the particular particle size range instantly claimed.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was

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not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

6. Claims 16-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over CA 2,068,366 (366) in combination with either US 4,808,411 (411) or US 5,707,646 (646) each.

This rejection is maintained for reasons of record in the Office Action mailed May 7, 2001, paper no. 27. CA '366 discloses particles comprising a core containing at least one pharmaceutically active ingredient with a continuous coating on the core (abstract). The coating comprises about 10-80% of the formulation (page 4, lines 15-23). The particle size of the core is about 0.1 to 250 microns, more preferably about 35-125 microns (page 4, line 38 to page 5, line 4). The coating thickness is about 0.005-25 microns (page 5, lines 5-10). For paracetamol as the pharmaceutically active ingredient, see page 5, line 16. For ethyl cellulose as the coating, see page 8, lines 21-27). At page 13, lines 1-23, CA '366 teaches a process of making the particles comprising suspending or dispersing the pharmaceutically active ingredient in the coating solution and spray-drying the suspension. See also example 1 at page 17, line 30 to page 18, line 7, which teaches spray-drying a solution of ethylcellulose and paracetamol. The powder obtained exhibited taste masking and sustained release of the paracetamol.

CA '366 does not specifically teach clarithromycin, spherical particles or the aspect ratio of the particles.

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US '411 discloses antibiotic/polymer complexes. A suitable antibiotic for use in the complexes is 6-O-methylerythromycin (clarithromycin). See the abstract. The complexes provide slow release of the antibiotic in order to mask the bitter taste (col. 4, lines 24-27). The antibiotic/polymer complexes can be provided in a dry, solid form, preferably in the form of particles (col. 4, lines 36-38). The particle diameter of the complexes may be smaller than 297 microns, which encompasses the particle size ranges instantly claimed. See also Example 5 at column 6 for a particle size of 60 mesh (250 microns). The complexes may be further coated with a polymer such as ethyl cellulose (col. 4, lines 57-61). Example 6 at column 6 teaches spray-drying a complex comprising clarithromycin with a coating.

US '411 teaches that clarithromycin has a bitter taste and is suitable for administration in particles that contain a polymer coating in order to provide sustained release and taste-masking. US '646 teaches that clarithromycin is a bitter tasting pharmaceutical that may be administered as particles containing a polymeric coating in order to provide taste masking.

It is within the skill in the art to select optimal parameters, such as the shape and aspect ratio of particles, in a composition in order to achieve a beneficial effect. *In re Boesch*, 205 USPQ 215 (CCPA 198). All of the references obtain the same results desired by Applicants, specifically taste-masking and sustained release. Therefore, absent evidence of unexpected results, the shape and aspect ratio of the particles are not considered critical to the invention.

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It would have been obvious to one of ordinary skill in the art at the time of the invention to prepare the particles of CA '366 using clarithromycin as the oral penicillin as taught by either US '411 or US '646 in any suitable shape expecting to provide a formulation of clarithromycin that can be administered orally that exhibits acceptable taste-masking and sustained release.

Response to Arguments

Applicant's arguments filed January 16, 2002 have been fully considered but they are not persuasive.

Applicant argues that the combination of references is improper because each reference is directed to a different technique. It is *prima facie* obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition which is to be used for the very same purpose. *In re Kerkhoven*, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980). The idea of combining them flows logically from their having been individually taught in the prior art. *In re Crockett*, 279 F.2d 274, 276-77, 126 USPQ 186, 188 (CCPA 1960). The references are directed to the same field of endeavor, pharmaceutical particles, and are addressing the same problems, sustained-release and/or taste masking. Claims 16-26 are directed to a product. The process by which the product is made does not provide patentability to the product. Claims 27-30 are directed to a method of mixing a core element and a coating in a diluent and then spray drying the mixture to form a powder. The references teach these two steps as discussed in the 35 U.S.C. 103(a) rejections above.

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The Declaration filed January 16, 2001 has been considered but is not persuasive. The declaration does not provide any data showing unexpected results over the prior art products. Only anecdotal evidence is provided to support declarant's conclusion regarding unexpected benefits residing in the claimed invention.

Applicant avers the presence of unexpected benefits in the claimed subject matter, yet fails to illustrate such. Evidence as to unexpected benefits must be "clear and convincing" *In re Lohr*, 137 USPQ 548 (CCPA 1963), and be of a scope reasonably commensurate with the scope of the subject matter claimed, *In re Linder*, 173 USPQ 356 (CCPA 1972). The data provided by Applicants, in the instant specification is neither clear, nor convincing nor reasonably commensurate in scope with the instant claims. The data provided in the instant specification in Table 2 does not compare the instant invention with the closest prior art. The prior art teaches coated tablets. Applicant has provided data comparing the instant invention with an uncoated tablet. There is nothing unexpected in obtaining sustained release using a coated tablet versus and uncoated tablet. Absent claims commensurate with the showing of unexpected benefits, or a showing reasonably commensurate with the instant claims, such claims remain properly rejected under 35 USC 103. Examiner would welcome claims directed to subject matter illustrated as possessing unexpected benefits.

In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was

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within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alysia Berman whose telephone number is 703-308-4638. The examiner can normally be reached Monday through Friday between 9:00 am and 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan, can be reached on 703-305-1877. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 or 703-872-9307 for after-final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1234 or 703-308-1235.


Alysia Berman
Patent Examiner
October 2, 2002


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